REMARKS

The foregoing amendments and the following remarks are submitted in response to the communication dated April 20, 2010.

Status of the Claims

Claims 17, 23, 30 and 31 are pending in the application. Claims 17, 23, 30 and 31 have been amended in order to more particularly point out and distinctly claim that which Applicants regard as the invention. Support for the amended claims and new claims can be found generally through Applicants' specification and/or in the previously pending claims. In particular, support for the term "lytic enzyme" in claims 17, 23, 30 and 31, particularly with reference to Pal or Cpl-1, can be found throughout the specification, including at paragraph [0008] (paragraph numbers from the published PCT application are noted). Support for the amendments to claims 17 and 23 can be found throughout the specification, including at paragraphs [0033], [0034], [0122], [0123], Figure 2 and Figure 3. Support for the amendments to claims 30 and 31 can be found throughout the specification including in paragraphs [0032], [0120], [0121] and in Figure 1.

With respect to all amendments and canceled claims, Applicant has not dedicated or abandoned any unclaimed subject matter and, moreover, has not acquiesced to any rejections and/or objections made by the Patent Office. Applicant reserves the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

Claim Rejections - 35 USC § 112, First Paragraph

Claims 17, 23 and 30-31 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time of filing. Applicants respectfully disagree and traverse this rejection.

The Examiner alleges that no basis or support is found in the specification for "wherein Pal and Cpl-1 are present at 0.5 minimal inhibitory concentration (MIC) or less and the combination demonstrates a bacterial titer reduction of ≥ 2 $\log_{10}$ greater than the single Pal or Cpl-1 agents", asserting that it is not apparent that an open ended or infinite bacterial titer reduction is disclosed. Without acquiescing to the Examiner and without prejudice to further or future prosecution, Applicants have above amended claims 17 and 23 including to refine the language of the claim to add clarity and particularity of reference. The relevant claims, claims 17 and 23 including as above amended, refer to a particular MIC concentration range (0.5 MIC or less of each agent Pal and Cpl-1 in the claimed combination) and a particular pneumococcal bacterial titer reduction of at least 2 logs when compared to the same MIC concentration of either single agent. The instant language is supported in the specification, including in Example 3, Figure 2, Figure 3, paragraphs [0033], [0034], [0122] and [0123]. Applicants particularly note that these described and depicted studies and results include assessment of 0.5 MIC and 0.25 MIC as described in the specification and shown in Figure 2 and in Figure 3 and that each of these MIC combinations demonstrated the synergistic effect as defined as demonstrating a titer reduction of at least 2 logs for the combination compared to the/either single agent alone. Applicants point out that the claim requires that the limitations of both the recited MIC concentration and the recited titer reduction be met by the claimed composition combination.

The Examiner alleges that no basis or support is found in the specification for the recitation "comprising a mixture of Pal and Cpl-1 at a concentration of 0.5 U/ml wherein the killing efficacy of the mixture is increased by greater than 1 $\log_{10}$ compared to 1 U/ml of Pal or Cpl-1 alone" as in claims 30 and 31. The Examiner particularly remarks that the "killing efficacy" target is not disclosed, and also that it is not apparent that an open-ended or infinite killing efficacy is disclosed. Without acquiescing to the Examiner and without prejudice to further or future prosecution, Applicants have above amended claims 30 and 31 including to clarify that the killing efficacy target is *Streptococcus pneumoniae.* Applicants further point out that the recited and rejected claim language is not open-ended, but specifically refers to and recites a particular concentration of each of the lytic enzymes Pal and Cpl-1, and the relative activity of the particular combination versus a particular and specific amount of a single agent of

Pal or of Cpl-1. A particular relative increased killing efficacy is referred to, as supported by the specification. This claim language is fully supported and finds basis in the specification, including at paragraphs [0032], [0120] and [121]. In particular, paragraph [0121] includes and states the following:

> ***[0121]*** *In 30 seconds 1U/ml Pal reduced the bacterial titer of the 4 strains by Log_{10} CFU/ml (median range) 1.34 (0.38 -1.81), while Cpl-1 at 1U/ml reduced the titers by log_{10} CFU/ml 0.83 (0.52 -1.31). The combination of both enzymes reduced the titers by log_{10} CFU/ml 2.40 (0.98 - 3.34) (Figure 1). After 10 minutes, reduction was log_{10} CFU/ml (median range) 1.99 (0.73 - 2.54), 1.44 (1.32 - 2.65), and 3.15 (2.50 - 5.28), for Pal, Cpl-1 and the combination respectively. In other words, mixing 0.5U/ml of each enzyme increased killing efficacy by log_{10} 1.07 to 131 (median, 30s and 10 min), compared to Pal alone and by log_{10} 1.58 to 1.72 (30s and 10 min), compared to Cpl-1 alone.*

Applicants submit that, contrary to the Examiner's allegation, the language of claims 30 and 31, including as above amended, is precise and clear and has basis and support in the specification.

The Examiner further alleges that no clear basis or support is found in the present specification for the language of "anti pneumococcal lytic enzyme" with respect to Pal or Cpl-1. Without acquiescing to the Examiner and without prejudice to further or future prosecution, Applicants have above amended each of claims 17, 23, 30 and 31 to remove this language and to refer to each enzyme as a lytic enzyme. The language "lytic enzyme" is clearly supported in the specification, including at paragraph [0008], particularly with regard to each of Pal and Cpl-1.

In view of the foregoing amendments and remarks, Applicants respectfully request that the Examiner withdraw the rejections under 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 112, Second Paragraph

Claims 17, 23 and 30-31 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicants respectfully disagree and traverse this rejection, submitting that claims 17, 23, 30 and 31 are clear and definite.

Claims 17 and 23 are rejected as lacking antecedent basis for "demonstrates a bacterial titer reduction" since the bacteria are not identified with regularity. In addition, the concentration of the single Pal or Cpl-1 agents is not identified, the Examiner asserts. Further,

claims 17 and 23 are rejected as vague, indefinite, inconsistent and contradictory in the recitation of "≥ 2 $\log_{10}$ greater". Without acquiescing to the Examiner and without prejudice to further or future prosecution, Applicants have above amended each of claims 17 and 23, including to particularly identify the bacteria, clarify the concentrations of each single agent, and to recite "at least 2 $\log_{10}$ greater".

The phrase "comprising a mixture of Pal and Cpl-1 at a concentration of 0.5 U/ml wherein the killing efficacy of the mixture is increased by greater than 1 $\log_{10}$ compared to 1 U/ml of Pal or Cpl-1 alone" in claims 30 and 31 is rejected as not specifying whether 0.5 U/ml pertains to each enzyme or both together. In addition, the target of the killing efficacy is not disclosed. Without acquiescing to the Examiner and without prejudice to further or future prosecution, Applicants have above amended each of claims 30 and 31, including to particularly identify the target of the killing efficacy, and to clarify that 0.5 U/ml refers to the concentration of each of Pal and Cpl-1 in the combination composition.

Lastly, the claims are rejected as confusing in the recitation of "anti pneumococcal lytic enzyme" with respect to Pal or Cpl-1. Applicants have above amended each of claims 17, 23, 30 and 31, without acquiescing to the Examiner and without prejudice to further or future prosecution, to refer to "lytic enzyme" with respect to Pal and Cpl-1.

Applicants respectfully submit that claims 17, 23, 30 and 31, including as above amended, are clear and definite.

In view of the above amendments and remarks, Applicants submit that the rejections of claims 17, 23 and 30-31 under 35 USC 112, second paragraph, have now been fully addressed and request their withdrawal.

The 35 USC § 103 Rejection

Claims 17 and 23 are rejected under 35 USC 103(a) as being unpatentable over Fischetti et al (I) (US Patent No. 6,264,945) taken with Marova et al (Folia Microbiol 38(3):245-252 (1993)), Fischetti et al (II) (US Patent 6,056,954), Sanz et al (Eur J Biochem 187:409-416 (1990)) and Loeffler et al (Science 294:2170-2172). The Examiner alleges that it would have been obvious to one of skill in the art to modify the composition of Fischetti et al (I) by replacing

the degradative enzymes therein with bacteriophage derived degradative enzymes as taught by Fischetti et al (II) and as suggested by the teaching of Loeffler et al and Sanz et al for the expected benefit of providing anti-microbial compositions having powerful degradative activity and suitable for the control of the dangerous and resistant bacterial pathogen P. (sic) pneumoniae. Applicants respectfully disagree and traverse this rejection.

To establish a prima facie case of obviousness, the prior art references must teach or suggest all the claim limitations. Applicants again underscore that the cited references do not, alone or in combination, teach or suggest the claimed compositions. The instant claims are directed to compositions comprising particular amounts of specific lytic enzymes obtained from bacteria having set out and specified desired effects and capabilities as to bacterial titer reduction of killing efficacy against explicit and defined bacteria. The particular and specific compositions of claims 17, 23, 30 and 31 are not made obvious by Fischetti et al (I) taken with Marova et al, Fischetti et al (II), Sanz et al, and/or Loeffler et al. Nothing in the cited references or in a combination thereof specifically teaches or leads one of skill in the art to be taught or suggested the specific synergistic activity and capability of the particular combinations of lytic enzymes as claimed. Applicants submit that claims 17, 23, 30 and 31, including as above amended, are not taught or suggested by a combination of Fischetti et al (I), taken with Marova et al, Fischetti et al (II), Sanz et al and Loeffler et al.

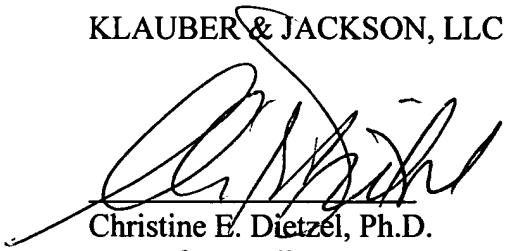
In view of the above remarks and amendments, Applicants submit that the 35 USC 103(a) rejection may properly be withdrawn.

No fees are believed to be necessitated by the foregoing Response. However, should this be erroneous, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or credit any overages.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the file history of the instant Application. The Claims as amended are believed to be in condition for allowance, and reconsideration and withdrawal of all of the outstanding rejections is therefore believed in order. Early and favorable action on the claims is earnestly solicited. The Examiner is invited to contact the undersigned at the below noted telephone number in order to address any remaining issues or questions and to effect their resolution.

Respectfully submitted,
KLAUBER & JACKSON, LLC



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